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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,400	12/03/2003	Kenneth A. Jones	AQMED.0102	5601

22858 7590 08/28/2006

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/726,400	JONES ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-6,12-17 and 27-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11 and 18-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-31* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 27-31 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The newly presented method claims do not require the particulars of the claimed apparatus, indicating that the claimed method may be performed with a materially different apparatus.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

2. The amendment filed 6 July 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a mechanical flow indicator that indicates direction of fluid flow within the valve, as claimed in newly presented claim 19.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant attempts to claim a mechanical flow indicator that indicates direction of fluid flow within the valve. However, applicant's disclosure with regard to the indicator, found at paragraph 0024 of US 2004/0111058 A1, discloses only a mechanical pop-up button that is not disclosed as having any means for indicating the direction of fluid flow through the valve. Accordingly, applicant has not sufficiently described the limitations of the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 7, 8, 9-11, 23, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,697,904 to Raines et al.

In the specification and figures, Raines discloses the apparatus as claimed by applicant. Specifically, Raines discloses a valve for a medical fluid device comprising first and second inlet ports 91 and 93, and outlet port 92 wherein the two inlet ports are arranged at an acute angle from one another (see column 15, lines 10-54, FIG 15). The inlet ports feature pressure-activated check valves that allow fluid flow in the direction of the outlet, preventing reverse fluid flow.

With regard to applicant's claim limitations drawn to the operation of the claimed valve (allowing fluid to pass in particular directions, relieving pressure, adjusting opening pressures), such limitations are held to be recitations of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 9, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,697,904 to Raines in view of US 4,304,257 to Webster.

In the specification and figures, Raines discloses the device substantially as claimed by applicant with the exception of a visual indicator of fluid flow in the valve. Webster discloses a medical fluid valve that comprises a transparent face plate 120 that allows an operator to visually assess blood flowing through the valve (see column 4, lines 42-60). Therefore, it would have been obvious to provide the valve disclosed by Raines with a transparent portion as disclosed by Webster in order to allow an operator to visually assess the flow of blood through the valve, as taught by Webster.

9. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,697,904 to Raines in view of US 4,838,338 to Priem.

In the specification and figures, Raines discloses the device substantially as claimed by applicant with the exception of a mechanical indicator of fluid flow in the valve. Priem discloses a fluid flow device that comprises a valve and a flow indicator comprising a mechanical flapper that provides the operator with a visual indication that fluid is flowing through the valve (see column 5, lines 37-50)

With regard to applicant's recitation drawn to the operation of the indicator to indicate a direction of flow through the device, such a limitation is a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the Priem device is capable of flapping in opposite directions to indicate the direction of flow in the device, meeting the limitations of the claims.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the mechanical flapper disclosed by Priem to the fluid flow valve disclosed by Raines in order to provide the operator visual indication of fluid flowing through the valve, as taught by Priem.

10. Claims 20, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,697,904 to Raines in view of US 4,747,826 to Sassano.

In the specification and figures, Raines discloses the device substantially as claimed by applicant with the exception of an electronic flow detector connected to a visual display. Sassano discloses a fluid flow system for rapid venous infusion that comprises tubing, valves, and means for sensing fluid flow. The device comprises fluid flow controllers 38 (which may include valves) and monitors coupled to infusion pump 14 (see column 4, lines 14-26). The flow sensors are electronic in nature and have a corresponding visual display (see column 6, lines 23-30). The system, including its sensors and controllers, allow for rapid, automated infusion to a patient that can be monitored by an operator consulting the display (see column 2, lines 16-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple an electronic fluid sensor with visual display, as disclosed by Sassano, with the valve disclosed by Raines in order to provide for easy fluid flow monitoring by a single operator, as taught by Sassano.

11. Claims 22, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,758,224 to Siposs et al in view of US 5,697,904 to Raines.

In the specification and figures, Siposs discloses the device substantially as claimed by applicant. With regard to claim 26, Siposs discloses a suction control valve with first inlet 42, a second inlet 32, and an outlet 20. The first inlet is regulated by a duckbill valve 44 that allows only one- way fluid flow. The second inlet allows fluid (such as atmospheric gas) to pass from a source (the atmosphere) in the valve towards the outlet in the event the vacuum in outlet 20 goes too far below atmospheric pressure (see FIG 1, column 3, lines 5-67).

With regard to claim 22, Siposs further discloses relief passages 28, 30, that act as expelling outlets that permit fluid flow to open air (see column 4, lines 48-57).

Siposs fails to disclose that the first and second inlet have an axis of less than 90 degrees between them. However, Raines discloses a two-inlet valve with the inlets disposed at an acute angle from one another (see FIG 15). It would have been an obvious matter of design choice to form the inlets disclosed by Siposs in the acute angle shape disclosed by Raines, since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. See MPEP 2144.04 (IV)(B).

12. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,758,224 to Siposs et al in view of US 7,033,336 to Hogendijk et al in view of US 5,697,904 to Raines.

In the specification and figures, Siposs discloses the device substantially as claimed by applicant (see rejection above) with the exception of providing a venous

reservoir as the source of fluid for the second inlet passage. With regard to claim 22, Hogendijk discloses a catheter assembly with a first inlet 258 and a second inlet 224, and an outlet passage 213 wherein the second inlet is coupled to a venous return line (see column 7, lines 45-67, column 8 lines 1-8, FIG 6C). The second inlet is regulated by a valve 256 that opens if the negative pressure in outlet line 213 is too great, allowing for pressure relief such that high levels of suction related aspiration will not harm the patient's vessel (see column 3, lines 45-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a venous reservoir or source as disclosed by Hogendijk to the valve apparatus disclosed by Siposs in order to prevent suction-related harm to the patient's vessel, as taught by Hogendijk.

Siposs and Hogendijk fail to disclose that the first and second inlet have an axis of less than 90 degrees between them. However, Raines discloses a two-inlet valve with the inlets disposed at an acute angle from one another (see FIG 15). It would have been an obvious matter of design choice to form the inlets disclosed by Siposs and Hogendijk in the acute angle shape disclosed by Raines, since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. See MPEP 2144.04 (IV)(B).

Response to Arguments

13. Applicant's arguments filed 6 July 2006 have been fully considered but they are not persuasive.

14. Applicant argues that applicant's language directed to the operation of the valve is not an intended use recitation, but rather a functional recitation of the function of the valve, and that applicant's specification teaches structural limitations that perform the claimed functions of the valve.

However, MPEP 2114 clearly requires that patentability requires structural differences from the prior art. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. In re Schreiber, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). "[A]pparatus claims cover what a device is, not what a device does." Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original).

In the instant case, applicant has not presented, in the claims, any structural limitations that distinguish the instant invention from the cited prior art. It is noted that the features upon which applicant relies (e.g., an umbrella valve) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant also argues in the same vein that Examiner has not identified any disclosure in Raines that suggests restricting fluid flow in any manner. However,

applicant's claims never recite that the second inlet comprises any such flow restricting means. A free-flowing valve allows fluid to flow in the direction of least pressure, which is all applicant sets forth in the claims.

The Raines valve is capable of performing the functions claimed by applicant, and meets the limitations of the claims as currently presented.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
18 August 2006

TATYANA ZALUKAEVA
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